

invention at the time the application was filed, and (2) allegedly failing to provide an enabling disclosure. The Examiner made the following observations by way of explanation:

While the specification is enabling for the 'chemical moiety' as defined by the structural formula in original claim 1, the specification does not reasonably provide enablement for the 'assay reagent composition' and 'system' of claims 21-23. . . . There is no enabling disclosure in the specification to establish definitions of the terms 'an assay reagent composition', 'a chemical moiety', 'a system', 'a reagent mixture', and 'an agent'. Also, there is no generic description in the specification to define the required components of the 'assay reagent composition' and 'system' (Official Action at 2-3).

Further, claims 21-23 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite, as "it is unclear exactly what is meant by . . . [these] terms even when the claims are read in light of the specification" (Official Action at 3).

Applicants respectfully traverse these rejections for the reasons below.

In view of the Examiner's comments, it may be helpful to provide a description of the present invention. Briefly, the specification discloses methods and compositions for qualitative and quantitative chemical analysis using chemical reagents comprising chemical moieties that can be used to detect small quantities of complex substances in a solution, such as pharmaceuticals, metabolites, and microorganisms (see the Field of the Invention on page 1 of the specification).

The chemical moieties used in the disclosed methods are described generically and specifically on pages 8-16 of the specification. The chemical moieties consist of a compound of the formula $(MPL^1L^2(-\text{link-}))_tB$, wherein M is a lanthanide metal, P is a polydentate ligand of the metal, L^1 and L^2 are ligands of the metal, t is an integer, (-link-) is a bond or bonds that connect B to P, L^1 , and L^2 , and B is a biological or nonbiological substance. Pages 8-16 of the

subject specification provide a detailed explanation of the various metals, ligands, and biological substances that may be used in a chemical moiety of the invention.

The chemical moiety is capable of emitting electrochemiluminescence upon exposure to electrochemical energy. The emission of electrochemiluminescence enables the chemical moiety to be detected in solution (see page 20 of the specification). The chemical moiety will emit electrochemiluminescence when it is in solution with an oxidizing agent or reducing agent. The oxidizing agent and/or reducing agent is a potential energy source, as it is reduced or oxidized upon exposure to electrochemical energy, and when reduced or oxidized, it transfers energy to the chemical moiety so that it can electrochemiluminesce. Therefore, when the chemical moiety is in solution with either of these agents, i.e., when the chemical moiety is a part of a reagent mixture, such as that described on page 24, lines 10-14, and the reagent mixture is exposed to electrochemical energy, the agent will be reduced or oxidized and it will transfer energy to the chemical moiety so that it can electrochemiluminesce and can be detected (see page 24 of the specification). Suitable oxidizing and reducing agents are described on pages 24-25 of the subject specification).

The chemical moiety may be used to detect the presence of an analyte of interest in solution. This aim is accomplished by including in the chemical moiety a biological or nonbiological substance, B, that is capable of binding to an analyte of interest, i.e., forming a specific complex with the analyte of interest (see pages 21-23 of the specification). For example, the analyte of interest may be a serum-derived antibody or a monoclonal antibody, in which case B may be an antigen which binds to that antibody. Therefore, once the chemical moiety is exposed to the analyte of interest, a binding interaction can occur and the chemical moiety can be detected by electrochemiluminescence as described above.

The present invention provides a system to accomplish these goals (see pages 26-28 of the subject specification). The system consists of a reagent mixture comprising the chemical moiety, a means for inducing the chemical moiety to emit electromagnetic radiation (i.e., an oxidant or reductant in the reagent mixture), a means for exposing the reagent mixture to electrochemical energy, and a means for detecting the emitted electrochemiluminescence.

In view of the foregoing description, which includes specific page and line references to the specification to show where this description of the invention is taken from, it should be evident that the Section 112 rejections are improper. The specification clearly describes a composition or reagent mixture comprising a chemical moiety and an agent, which interacts with the chemical moiety and enables the chemical moiety to emit electrochemiluminescence. The terms "chemical moiety", "system", "reagent mixture", and "agent" are clearly defined and taken directly from the subject specification. As for the term "assay reagent composition", Applicants submit that the skilled artisan will plainly understand that this term refers to a composition for use in an assay wherein the composition consists of one or more reagents used in the assay. Thus, these terms are plainly enabled and definite, and the specification clearly shows that the Applicants were in possession of the invention at the time the application was filed.

In view of the foregoing remarks, favorable reconsideration and withdrawal of the Section 112 rejections are respectfully requested.

Double Patenting Rejection

Claims 21-23 were rejected under the judicially created doctrine of obviousness type double patenting as allegedly unpatentable over the claims of U.S. Patent No. 5,858,676. The

Examiner asserted that the claims are not patentably distinct because the instantly claimed reagent has the method of the issued patent as its sole utility.

Without conceding the propriety of the rejection, Applicants request that the instant rejection be held in abeyance pending the determination of allowable subject matter. If, at that time, Applicants determine that the filing of a terminal disclaimer is warranted, they will take such action in order to obviate the instant rejection.

Rejection Under 35 U.S.C. § 102(b)/(e)

Claims 21-23 were rejected under 35 U.S.C. § 102(b)/(e) as anticipated by Kankare (GB 2,217,007), Bard (U.S. Patent No. 5,310,687), Kamin (U.S. Patent No. 5,147,806), or Weber (U.S. Patent No. 4,293,310).

Applicants respectfully traverse this rejection for the reasons below.

The instant claims relate to a composition comprising an agent and a chemical moiety, wherein the chemical moiety is (i) not oxidized or reduced upon exposure to the required level of electrochemical energy; and (ii) capable of emitting electrochemiluminescence. Further, the chemical moiety has the formula $(MPL^1L^2-(-link-))_tB$, wherein each of the components are as defined above. None of these elements of the instant invention are disclosed in the cited references. Therefore, the references cannot anticipate the claimed invention.

Favorable reconsideration and withdrawal of the Section 102 rejections are respectfully requested.

Conclusion

In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

WHITMAN BREED ABBOTT & MORGAN LLP
200 Park Avenue, New York, NY 10166
Attorneys for Applicants

By: Pamela C. Ancona
Barry Evans
Reg. No. 22,802
Pamela C. Ancona
Reg. No. 41,494
(212) 351-3000